REMARKS

Applicants thank the Examiner for the interview of August 13, 2009. As discussed in the interview, claims 1, 3-15, 32-33, and 35-37 remain pending in the application. Claims 1, 3-4, 13-14, and 35-37 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Publication No. 2005/0043644 to Stahmann et al. ("Stahmann"). Claims 5-6 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Stahmann in view of U.S. Patent No. 5,540,733 to Testerman ("Testerman"). Claims 7-8, 15, and 32-33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Stahmann in view of U.S. Patent No. 5,207,230 to Bowers ("Bowers"). Claims 9-12 stand rejected 35 U.S.C. § 103(a) as being unpatentable over Stahmann and Bowers in view of U.S. Publication No. 2002/0049479 to Pitts ("Pitts"). Testerman, Bowers, and Pitts were all cited in a January 2009 Office Action, to which Applicants responded in April 2009.

The present invention is directed to an implantable device and methods of treating sleep disordered breathing with the implantable device, wherein the device includes a detector to detect changes in transthoracic impedance, a stimulator, a real time clock, and a postural sensor. The treatment is in the form of electrical or mechanical stimulation of afferent nerves. All of the methods of the present invention detect aspects of a patient's real time condition and provide two different modes of stimulation, with the mode of stimulation based upon the patient's detected condition. As discussed in detail during the interview, the two modes of stimulation are not disclosed in the cited art. In the methods of the present invention, the sleep state of the patient is determined at least in part based on both the real time clock

and the postural sensor. When the patient is determined to be asleep, stimulation is provided prophylactically so as to prevent airway collapse or to increase tone of upper airway muscles (Mode I). The detector of the device also emits high frequency pulses, detects transthoracic impedance consequential to the pulses, and determines changes to the transthoracic impedance which are indicative of an obstruction. If an obstruction is determined to be present, the stimulation is increased (Mode II).

All claims stand rejected, at least in part, as unpatentable under 35 U.S.C. § 103(a) in view of Stahmann. Stahmann is directed to an approach for predicting disordered breathing (see Abstract). Stahmann identifies parameters which may be indicative of disordered breathing (see Tables 1-2 and ¶ 0044). However, Stahmann does not disclose how to use those parameters in a treatment for sleep disordered breathing or obstructive sleep apnea. Stahmann does not disclose or suggest any particular step-by-step method for treating obstructive sleep apnea other than generally referring to overcoming decreased muscle activity of the tongue. (See paragraph 0031 of Stahmann, which states that "treatment for obstructive sleep apnea involves compensating for the decreased muscle activity by electrical activation of the tongue muscle ... [by applying] electrical stimulation to the hypoglossal nerve.") Stahmann does not disclose or suggest how, when, or under what conditions to apply electrical stimulation to the hypoglossal nerve. As discussed in the interview, Stahmann does not disclose providing dual mode stimulation. In addition, Stahmann does not disclose or suggest any apparatus or method even remotely similar to the apparatus and method of the present invention.

In particular, Stahmann does not disclose or suggest several attributes of the present invention, including 1) determining the patient's real time condition, 2) a detector to detect transthopracic impedance, 3) detecting transthoracic impedance consequential to pulses, 4) providing two different modes of stimulation with the operative mode based upon the patient's condition, 5) determining the patient's sleep state, 6) how to determine the presence of an obstruction, 7) providing stimulation prophylactically, 8) a real time clock, or 9) an implantable device with all of the elements in the implantable device of the present invention. In summary, Stahmann clearly does not disclose or suggest the invention as defined by the claims.

With regard to the rejection of claims 5 and 6, which depend from claim 1, the Examiner primarily relies on Stahmann and further relies on Testerman for disclosing the limitation that the electrical stimulation is comprised of a train of electrical pulses, the Examiner arguing that it would be obvious to use a train of pulses in order to extend battery life. But as detailed above, Stahmann does not disclose or suggest several steps in the method of claim 1. In addition, although Testerman may discuss trains of pulses, such discussion is clearly not in the context of the present invention. Further, in response to the January 2009 Office Action, Applicants acknowledged that Testerman teaches a method of treating sleep disordered breathing comprising the steps of delivering treatment so as to prevent airway collapse if the patient is asleep, determining the presence of an obstruction in the patient's airway, and if an obstruction is present increasing the treatment until the obstruction is no longer present, wherein the treatment comprises applying electrical

stimulation of afferent nerves and the presence of an obstruction is determined by sensing a change in transthoracic impedance. However, Testerman does not disclose an implantable device with any real time clock or even use of time of day. Testerman also does not determine whether the patient is asleep by combined use of time and a postural sensor. Testerman's device needs to be activated before the patient is asleep by use of a power-on reset or manual reset. Testerman assumes a sleep state once a predetermined time period expires after the device is turned on. Once turned on, the device in Testerman imposes a delay before starting any stimulation, whereas the present invention does not require a time delay. Further, Testerman does not disclose starting stimulation in response to the patient being asleep but rather only after (1) the device is turned on, (2) a prescribed delay has taken place, and (3) the presence of an "event" has been determined. (see col. 15, ln. 9-16). In Testerman, all three of the aforementioned conditions must be satisfied before stimulation is provided. Furthermore, Testerman's method for determining the presence of an event is nothing like the change in thoracic impedance method of the present invention. Testerman determines the onset of an event by "moitoring changes in respiratory effort waveform" based upon "averag[ing] over successive respiratory cycles." (see Testerman Abstract). Also, because Testerman only discloses beginning stimulation upon determining the presence of an event, it does not disclose the bi-modal approach of the present invention or prophylactically providing stimulation. Testerman does not disclose or suggest any kind of bi-modal operation, much less that of Applicants. Also, Testerman does not measure transthoracic impedance (or differences in transthoracic impedance) at all, let alone

to determine the onset of an event, nor does Testerman transmit high frequency pulses so as to detect transthoracic impedance change. Because Testerman is directed to something completely different from the present invention and Testerman does not disclose or suggest limitations found in the present invention (and neither does Stahmann). Testerman, in combination with Stahmann, does not preclude patentability of claim 5.

In addition, with regard to claim 6, the Examiner states that it would be obvious to use a 10-30 pulse train length. (¶ 6, citing In re Aller, 105 U.S.P.Q. 233). However, claim 6 depends from claims 1 and 5 and for the reasons previously discussed, because claims 1 and 5 are believed to be in condition for allowance in that neither Stahmann nor Testerman alone or together disclose or suggest the limitations of those claims, claim 6 should similarly be allowable.

In summary, there is no suggestion in either Testerman or Stahmann to include trains of pulses with the other limitations of the present invention.

Claims 7-12, 15 and 32-33 are rejected, at least in part, based on the combination of Stahmann and Bowers. The Examiner relies upon Bowers (col. 3, ln. 20-23, and col. 10, ln. 25-30) for the step of mechanical stimulation of nerves to increase muscle tone to reject claims 7-12 and 32-33 and for the mechanical stimulation element of claim 15. However, as detailed in Applicant's April 2009 correspondence, Bowers is directed to a sensor with a transducer film which attaches to a body portion to record mechanical forces or potentially to provide stimulation. Unlike the present invention, Bowers does not disclose or even discuss nerve stimulation to increase muscle tone, nor does Bowers disclose or suggest

numerous elements of the claims of the present invention. Bowers does not determine the sleep state of the patient in any way. Bowers does not disclose bi-modal use at all and, in particular, does not disclose bi-model use as detailed in the claims of the present invention. Bowers also does not determine the onset of an obstruction. More broadly, Bowers does not disclose or suggest the use of a sensor or any other device to treat sleep disorders. Further, Bowers does not suggest sensing changes in transthoracic impedance. In short, Bowers discloses a piezo-mechanical device but does not, alone or in combination with Stahmann, disclose or suggest use of a piezo-mechanical element in an implantable device such as in the present invention nor does it disclose or suggest the methods of the present invention. There also is no suggestion in Bowers to include mechanical stimulation in combination with the limitations of the present invention, just as Stahmann does not disclose or suggest the limitations of the present invention and does not disclose or suggest adding mechanical stimulation of nerves.

The Examiner relies in part on Pitts in combination with Stahmann and Bowers to reject claims 9-12. Regarding claim 9, the Examiner relies on Pitts solely based upon Pitts' disclosing a piezo-electric mechanical element implanted within or adjacent to the base of the genioglossus muscle. However, as previously detailed above, neither Stahmann nor Bowers discloses or suggests several limitations of the present invention. Also, Pitts does not disclose or suggest those same limitations and Pitts does not disclose or suggest implanting the device in combination with the other limitations of the present invention. For example, the Pitts' device does not include a real time clock, a postural sensor, or a detector to detect changes in

thoracic impedance. Pitts also does not provide bi-modal stimulation as defined in the present claims. In Pitts, the only stimulation is a low level stimulation and Pitts does not describe any increase or change in stimulation. Further, Pitts does not disclose how it determines the patient's sleep state other than "[t]he device(s) is turned on as the patient goes to bed." (¶ 0030). Pitts does not disclose a real time clock. The Pitts reference to "selected time of day" is not a disclosure or suggestion to use a real time clock and Pitts does not disclose or suggest that a clock and postural sensor are housed within an implantable device and used together for detecting a patient's sleep state. Without a real time clock or position sensor, the method of Pitts cannot be the method of the present invention. Finally, Pitts does not even disclose determining the presence of an obstruction.

With regard to the rejection of claims 10-11, the Examiner relies in part on Bowers (col. 10, ln. 25-30) and Pitts (¶ 0029) for disclosing that the duration of mechanical stimulation is on the order of several seconds of vibration. However, Bowers col. 10, ln. 25-30 says nothing as to duration of stimulation. The cited passage merely refers to applying a low frequency vibration to induce sleep and the benefit of mechanical stimulation as compared with electrical stimulation. Similarly the cited passage of Pitts does not refer to duration of stimulation either. Pitts ¶ 0029 merely refers to repetitive stimulation. Further, Pitts was cited in an earlier Office Action and Applicant's April 14, 2009 response details the inapplicability of Pitts as a reference. In addition to the reasons detailed above regarding Bowers and Stahmann not disclosing or suggesting limitations of the present invention, neither Bowers nor Pitts together with Stahmann discloses or suggests the

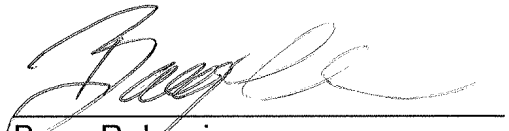
combination of limitations of the present invention. In summary, with regard to claims 9-11, the entirety of the limitations is not disclosed or suggested in Stahmann combined with Bowers and Pitts.

Although in paragraphs 11-12 of the Office Action claim 12 is rejected at least in part based on Bowers, no reason is given for basing the claim 12 rejection on Bowers. It is respectfully requested that the rejection of claim 12 be withdrawn.

In summary, even when combining Stahmann, Testerman, Bowers, and Pitts, in any combination, several features of the present invention which are not disclosed or suggested include an implantable device with all the claimed elements, including bi-modal stimulation, determining the presence of an obstruction, and determining the patient's sleep state. As a result, it is believed that claims 1, 3-15, 32-33, and 35-37 are in condition for allowance.

The allowance of claims 1, 3-15, 32-33, and 35-37 and the early passage to issue of the application are respectfully requested.

Respectfully submitted,
GOTTLIEB, RACKMAN & REISMAN



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